AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions, and listings, of claims in the application. Compared to prior versions, claims 33, 43, 63, 66, 67, and 68 are amended. Claims 36-41 are canceled without prejudice to their re-presentation in one or more progeny patent applications.

Listing of Claims:

1-32 (Canceled).

33. (Currently Amended) A bi-layer wax-film composite having a total thickness of less than 5 mm, comprising:

(a) a pH-sensitive mucoadhesive layer, comprising ~~consisting essentially of~~:

(1) at least one water-insoluble swellable anionic mucoadhesive polymer; and

(2) at least one anionic pH-sensitive film-forming ~~polymer~~ copolymer of methacrylic acid and acrylic or methacrylic ester;

(b) a water-insoluble pharmaceutical wax layer bonded to the pH-sensitive mucoadhesive layer; and

(c) at least one molecule of interest;

wherein the pH-sensitive mucoadhesive layer adheres to a wet mucosal surface for delivery of the molecule of interest thereto.

34. (Original) The wax-film composite of claim 33, wherein the pH-sensitive mucoadhesive layer is present at a concentration of 20% to 90% by weight, and the water-insoluble wax layer is present at a concentration of 10% to 80% by weight.

35-41. (Canceled).

42. (Original) The wax-film composite of claim 33, wherein the water-insoluble wax layer comprises at least one water-insoluble pharmaceutical wax having a melting point between 40° C and 100° C and at least one water-soluble or water-swellable polymer.

43. (currently amended) The water-insoluble pharmaceutical wax of claim 42, wherein said wax is ~~DENTSPLY® Utility Wax,~~ beeswax, emulsifying wax, microcrystalline wax, carnauba wax, paraffin wax, white wax, yellow wax, or other suitable pharmaceutical wax.

44. (Previously Presented) The water-soluble or swellable polymer of claim 42, wherein said polymer is present in the insoluble wax layer at a concentration from 0.05% to 10% by weight.

45. (Original) The water-soluble or swellable polymer of claim 42, wherein said water-soluble or water-swellable polymer is tragacanth, polyvinyl pyrrolidone, polyvinyl alcohol, cross-linked polyacrylic acid, polyethylene glycol, a cellulose polymer derivative, or other suitable pharmaceutical polymer that is water-soluble or water-swellable.

46. (Previously presented) The wax-film composite of claim 33, wherein the molecule of interest is contained in and released from either the pH-sensitive mucoadhesive layer or the water-insoluble wax layer.

47. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest comprises an active pharmaceutical compound, a sweetener, a flavoring agent, a diagnostic agent, or a combination thereof.

48. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is amlexanox.

49. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is triclosan.

50. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is lidocaine, benzocaine, or dyclonine.

51. (Previously presented) The wax-film composite of claim 33, wherein the molecule of interest is a peptide or protein.

52. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is at least one benzodiazepine drug or derivative thereof.

53. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is hirudin or hirudin complexed with a substance of opposite charge.

54. (Withdrawn) The wax-film composite of claim 53, wherein said substance of opposite charge is chitosan or protamine.

55. (Withdrawn) The wax-film composite of claim 33, wherein the molecule of interest is plasmid DNA or plasmid DNA complexed with a substance of opposite charge such as chitosan, protamine, or a cationic lipid.

56. (Previously Presented) The wax-film composite of claim 33, wherein the wax-film composite is applied to an application site comprising: the skin, mouth, vagina, nasal cavity, or other accessible mucosal site.

57. (Previously Presented) The wax-film composite of claim 56, wherein the wax-film composite adheres to the application site for at least one hour.

58-62. (Canceled)

63. (Currently amended) The wax-film composite of claim [[41]] 33, wherein the weight ratio of ~~Noveon~~ water-insoluble swellable anionic mucoadhesive polymer to ~~Eudragit~~ anionic pH-sensitive film-forming copolymer is from 2:1 to 4:1.

64. (Previously presented) The wax-film composite of claim 47, wherein the active pharmaceutical compound is an antimicrobial, an antiviral, an antiinflammatory, an antiseptic, an antihistamine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migraine or an antifungal.

65. (Previously presented) The wax-film composite of claim 33, wherein the water-insoluble wax layer comprises at least one water-insoluble pharmaceutical wax having a melting point between 40° C and 100° C.

66. (Currently amended) A bi-layer wax-film composite having a total thickness of less than 5 mm, comprising:

(a) a pH-sensitive mucoadhesive layer, comprising ~~consisting essentially of~~:

(1) at least one water-insoluble swellable anionic mucoadhesive polymer of polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol; and

(2) at least one anionic pH-sensitive film-forming ~~polymer~~ copolymer of methacrylic acid and acrylic or methacrylic ester;

(b) a water-insoluble pharmaceutical wax layer bonded to the pH-sensitive mucoadhesive layer; and

(c) at least one molecule of interest;

wherein the pH-sensitive mucoadhesive layer adheres to a wet mucosal surface for delivery of the molecule of interest thereto.

67. (Currently amended) A bi-layer wax-film composite having a total thickness of less than 5 mm, comprising:

(a) a pH-sensitive mucoadhesive layer, ~~comprising~~ consisting essentially of:

(1) at least one water-insoluble swellable anionic mucoadhesive polymer of polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol; and

(2) at least one anionic pH-sensitive film-forming ~~polymer~~ copolymer of methacrylic acid and acrylic or methacrylic ester;

(b) a water-insoluble pharmaceutical wax layer bonded to the pH-sensitive mucoadhesive layer; and

(c) at least one molecule of interest;

wherein the pH-sensitive mucoadhesive layer adheres to a wet mucosal surface for delivery of the molecule of interest thereto.

68. (Currently amended) A bi-layer wax-film composite having a total thickness of less than 5 mm, comprising:

(a) a pH-sensitive mucoadhesive layer, consisting of:

(1) at least one water-insoluble swellable anionic mucoadhesive polymer of polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol; and

(2) at least one anionic pH-sensitive film-forming ~~polymer~~ copolymer of methacrylic acid and acrylic or methacrylic ester;

(b) a water-insoluble pharmaceutical wax layer bonded to the pH-sensitive mucoadhesive layer; and

(c) at least one molecule of interest;

wherein the pH-sensitive mucoadhesive layer adheres to a wet mucosal surface for delivery of the molecule of interest thereto.